

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:

*The County of Trumbull v. Purdue Pharma,
L.P., et al.*, Case No. 18-op-45079,

and

*The County of Lake v. Purdue Pharma, L.P., et
al.*, Case No. 17-md-2804

“Track Three Cases”

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

OBJECTION TO DEFENDANTS’ RESPONSE

Plaintiffs Lake and Trumbull County, Ohio (collectively, “Plaintiffs”), respectfully submit this Objection to Defendants’ Response to Special Master Cohen’s October 26, 2020 Request. (Doc. 3550). Plaintiffs object to the Pharmacy Defendants’ proposal for the same reasons stated in Plaintiffs’ Response to Court’s Request for Input Regarding Statutes and Regulations to be Quoted in Jury Instructions (Doc. 3548) and Objections to Defendants’ Proposed Jury Instructions (Doc. 3449). The Court should reject Defendants’ proposal because it omits relevant provisions and interjects language that is not relevant to any issue to be decided by the jury and which is likely to lead to juror confusion. Defendants did include certain provisions that overlap with Plaintiffs’ proposal and would not be objectionable, if the additional, necessary context were provided. Plaintiffs attach hereto a redline of Exhibit B to Defendants’ Response (Doc. 3550-2), to clearly

identify those provisions that Defendants seek to include that Plaintiffs object to and those they can accept.¹

Defendants appear to agree with Plaintiffs, moreover, that quoting directly from the statutes and regulations is not the best approach. Plaintiffs continue to believe this might be inadvisable due to technical language and redundancies that may cause more confusion than clarity for the jurors, as well as the Court's ability to frame the legal requirements in plain language.

I. There Appears to Be Agreement on the Overall Approach.

Plaintiffs continue to believe that the preferred approach would be for the Court simply to instruct the jury in plain language as to what the law requires or prohibits. Defendants' submission confirms that, like Plaintiffs, they believe "[t]he meaning of statutes and regulations is a question of law for the Court, not a question to be decided by the jury." Doc. 3548 at 1-2 (Plfs' submission); *compare* Doc. 3550 at 2 (Defs' submission) ("The meaning of the statutes and regulations is a question of law, which must be decided by this Court, and it would be error to leave that inquiry to the jury."). Given the parties' agreement on this issue, the Court should use Plaintiffs' succinct and correct proposal.

Plaintiffs' proposed language is non-argumentative and not only consistent with, but intended to mirror, legal rulings the Court has already made concerning Defendants' statutory and regulatory duties. Specifically, Plaintiffs' proposal adopts language from the Court's summary judgment ruling concerning Defendants' duties under the

¹ To be clear, the attached redline does not, however, include additional provisions and contextual language that Plaintiffs proposed in their prior submission. Doc. 3548. For this reason, the two submissions should be reviewed together.

Controlled Substances Act as distributors and the Court's ruling on Defendants' motion to dismiss, which addresses arguments concerning their legal duties as dispensers. Defendants, by contrast, have not proposed any such plain language in their submission. *See* Doc. 3550. Although they included lengthy, argumentative, and irrelevant proposed commentary in their proposed jury instructions submitted in September, that commentary is both legally incorrect and a recipe for jury confusion. *See* Doc. 3449. If the Court adds to the instructions it previously proposed after affording the parties ample opportunity to comment, it should use Plaintiffs' proposed language. *See* Doc. 3548 at 3-4 (Plaintiffs' Recommended Approach).

II. Defendants' Proposed Citations Ignore Applicable Law and Interject Irrelevant Provisions Not at Issue.

If the Court considers it helpful to supplement an explanation with the relevant statutory and regulatory citations, Defendants' proposal is too narrow in omitting language on point to their violations. Concerning federal law, it is necessary, for example, to explain to the jury (if direct quotations are used), that "[e]xcept as authorized by [the federal Controlled Substances Act ("CSA")], it shall be unlawful for any person knowingly or intentionally to . . . distribute or dispense, or possess with intent to . . . distribute or dispense, a controlled substance," 21 U.S.C. § 841(a). Troublingly, Defendants omit *any* citation to Ohio statutes and regulations at all. The request to which Defendants were to respond called for views concerning "the federal and Ohio CSAs." Doc. 3550-1.

Defendants included certain provisions, shown on the attached redline, to which Plaintiffs would not object, (specifically, statutory definitions found in 21 U.S.C. § 802,

and language from 21 U.S.C. § 842(a)), contingent on inclusion of the additional contextualizing language suggested by Plaintiffs therein. Defendants' proposal includes certain ellipses and legal terms, and omissions that render their suggestion incomplete and potentially confusing, and Plaintiffs have proposed changes for the sake of clarity, without which Plaintiffs' would object. *See Exhibit.* Defendants have also included certain of the same language as did Plaintiffs.

The relevant provisions, however, are likely to be lost, and the jury confused by inclusion of, Defendants' proposal for a recitation of other provisions not at issue. *First*, as Plaintiffs' explained in their own submission, the "Security Requirements" that Defendants suggest the Court cite are irrelevant, as they do not set forth any duty of registrants at issue in this case. Rather, they relate to how the DEA determines whether a registrant has provided effective controls. If a referenced section is *not* applicable here, there is no reason to quote it, and its inclusion in jury instructions threatens to confuse the jury. This is particularly true, and quotation of this passage is especially inappropriate, because the Court has already rejected the inference/significance that Defendants argued attached to this language, and also already has decided what Defendants' obligations are. *See Opinion and Order Regarding Plaintiffs' Summary Judgment Motions Addressing the Controlled Substances Act, In re: National Prescription Opiate Litig.*, 2019 WL 3917575, at *7-9 (N.D. Ohio Aug. 19, 2019); Opinion and Order

[denying Defendants' motion to dismiss], *In re: National Prescription Opiate Litig.*, 2020 WL 4550400, at *6-13 (N.D. Ohio Aug. 6, 2020).²

Second, although Plaintiffs are not categorically opposed to including the language from 21 C.F.R. § 1306.04(a) with reference to “the pharmacist who fills the prescription,” if it is included, additional language is necessary. Plaintiffs are concerned that Defendants will attempt to twist this language in a way that confuses and misleads the jury by suggesting that “[e]mployment of a pharmacist” would “relieve a pharmacy or pharmacy owner of the obligation to ensure that only valid prescriptions are filled.” Opinion and Order [denying Defendants' motion to dismiss], 2020 WL 4550400, at *16. This Court rightly recognized that that is not the case. *See id.* at *6-7; *see also, e.g., Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*; Decision and Order, 77 FR 62316-01 (“When considering whether a pharmacy has violated its corresponding responsibility, the Agency considers whether the entity, not the pharmacist, can be charged with the requisite knowledge.”); *Top RX Pharmacy*; Decision and Order, 78 FR 26069, 62341 (DEA Oct. 12, 2012) (same); *cf. Jones Total Health Care Pharmacy LLC and SND Health Care LLC v. Drug Enforcement Administration*, 881 F.3d 82 (11th Cir. 2018); *accord Linden Med. Pharm. v. Ohio State Bd. of Pharm.*, 2001 Ohio App. LEXIS 2041, at *24 (Ohio Ct. App. 11th Dist. May 8, 2001) (explaining that “licensees electing to operate a business through employees are

² As Plaintiffs noted regarding the proposed passage concerning “substantial compliance” with security requirements, Plaintiffs also would object to this provision being quoted because empowerment of the DEA to overlook insubstantial violations of law does not mean the law has not been violated; it goes only to the regulatory consequences of those violations. As the DEA’s Rule 30(b)(6) designee testified in this litigation, shipping a suspicious order is a *per se* violation of federal law. Prevoznik Dep. Vol II, 632:7 to 633:2, April 18, 2019 (DEA 30(b)(6) designee).

responsible to the licensing authority for their conduct”). Without this explanation, Plaintiffs would object.

Third, production quotas are irrelevant to the jury instructions. As Defendants are well aware, the federal Controlled Substances Act (“CSA”) is designed to ensure that controlled substances within the quota are not diverted. *See In re Nat’l Prescription Opiate Litig.*, 2019 WL 3917575, at *1 & *8 (N.D. Ohio Aug. 19, 2019); *see also, e.g.*, Rannazzisi Dep., Vol. II at 498:24-499:25 (May 15, 2019). That manufacturers have quotas for “each basic class” of controlled substances, 21 U.S.C. § 846(a)(1) does not specifically address even whether they may make and sell a particular drug, such as oxycodone 30, that is frequently diverted, much less whether Defendants engaged in unlawful conduct. Quotas in no way excuse manufacturers, or distributors and pharmacies, from maintaining effective controls against diversion, or any other legal obligation. Defendants’ proposal to quote 21 U.S.C. § 846(a)(1) is a transparent attempt to distract from the law that applies to their conduct, and which sets a standard with which Plaintiffs allege they failed to comply.

Finally, Plaintiffs object to Defendants’ attempt, after already having had multiple opportunities to share their view, to reserve the right to “add additional language.” Doc. 3550 at 2. The legal requirements at issue are straightforward, and the Court has already issued relevant rulings. Defendants do not need a third bite at the apple.

III. Conclusion

Plaintiffs respectfully request that the Court instruct the jury consistent with Plaintiffs’ proposed instructions (which simply accept the language of the Court’s

instructions proposed in May 2020), or, if it is inclined to add language, add the language recommended by Plaintiffs. See Doc. 3548 at 3-4.

DATED: January 15, 2021

Respectfully submitted,

Paul J. Hanly, Jr.
SIMMONS HANLY CONROY
112 Madison Avenue, 7th Floor
New York, NY 10016
(212) 784-6400
(212) 213-5949 (fax)
phanly@simmonsfirm.com

Joseph F. Rice
MOTLEY RICE LLC
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
(843) 216-9000
(843) 216-9290 (Fax)
jrice@motleyrice.com

Paul T. Farrell, Jr.
FARRELL LAW
422 Ninth Street
Huntington, WV 25701
(304) 654-8281
paul@farrell.law

Plaintiffs' Co-Lead Counsel

W. Mark Lanier
LANIER LAW FIRM
10940 W. Sam Houston Pkwy N., Ste 100
Houston, TX 77064
(713) 659-5200
(713) 659-2204 (Fax)
wml@lanierlawfirm.com

Trial Counsel

/s/ Peter H. Weinberger
Peter H. Weinberger (0022076)
SPANGENBERG SHIBLEY & LIBER
1001 Lakeside Avenue East, Suite 1700
Cleveland, OH 44114
(216) 696-3232
(216) 696-3924 (Fax)
pweinberger@spanglaw.com

Plaintiffs' Liaison Counsel

Frank Gallucci
PLEVIN & GALLUCCI COMPANY,
L.P.A.
55 Public Square, Suite 222
Cleveland, OH 44113 (216) 861-0804
(216) 861-5322 (Fax)
FGallucci@pglawyer.com

Hunter J. Shkolnik
NAPOLI SHKOLNIK
360 Lexington Ave., 11th Floor
New York, NY 10017 (212) 397-1000
(646) 843-7603 (Fax)
hunter@napolilaw.com

*Counsel for Plaintiffs Lake County and
Trumbull County, Ohio*

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 15th day of January, 2021, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF system.

/s/ Peter H. Weinberger
Peter H. Weinberger
Plaintiffs' Liaison Counsel